

REMARKS/ARGUMENTS

The Examiner has objected to the specification under 35 U.S.C. 132(a) because it introduces new matter. The added matter has been deleted.

37 C.F.R. § 1.57 allows the incorporation of matter into the specification by reference. An incorporation by reference must be set forth in the specification and must express clear intent to incorporate by reference by using the root words “incorporat(e)” and “reference” (i.e., “incorporate by reference”) (37 C.F.R. § 1.57(b1)) and clearly identify the referenced patent, application, or publication (37 C.F.R. § 1.57(b2)). Any insertion of material incorporated by reference into the specification or drawings of an application must be by way of an amendment to the specification or drawings. Such an amendment must be accompanied by a statement that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter (37 C.F.R. § 1.57(f)).

The Tankovich patents were incorporated by reference in the original application on page 5, lines 21-23 and identified as U.S. Patent No. 5,423,803 and U.S. Patent No. 6,036,684. The specification is amended by the insertion of material from the incorporated by reference U.S. Patent No. 6,036,684 pursuant to 37 C.F.R. § 1.57. The material being inserted is the material previously incorporated by reference and the amendment to the specification contains no new matter.

The matter being inserted into the specification from U.S. Patent No. 6,036,684 is found in that patent at col. 4, lines 5-9 and lines 24-42 and col. 5, lines 43-39 and 62-64.

Claim Rejections 35 U.S.C. § 112

The Examiner states that the phrase “with one pass of laser light” in the claims does not have support in the specification. This phrase has been deleted from the claims.

The Examiner states that the phrase “does not remove skin or hair” does not have support in the originally filed application. Applicant respectfully disagrees. U.S. Patent No. 6,036,684 does disclose that the method of the present invention does not remove skin or hair (see below).

The specification has been amended pursuant to 37 C.F.R. to include the matter that supports this phrase, so this phrase is not new matter.

The Examiner states that the original specification recited "as the particles explode, they cause the removal of the stratum corneum and the mineral oil penetrates into the epidermis...". The use of the words "stratum corneum" was an error. The word that should have been used instead was "particles", i.e., the removal of the "particles", not the "stratum corneum". This is described in the incorporated reference U.S. Patent No. 6,036,684 in column 5, lines 44-47: "The first or second pulses clean substantially all of the mixture from the skin by violently fracturing the carbon particles". The originally filed specification is quite clear that the epidermis is left intact by the method of the present invention. That the epidermis is left intact is disclosed on page 1, lines 7-8; page 2, lines 18 and 20, page 7, line 14; page 10, lines 12 and 13; and page 17, line 7. One of ordinary skill in the art would know that if the epidermis is left intact there will not be removal of the stratum corneum. Fig. 2 of the originally filed specification shows the stratum corneum intact, the remainder of the epidermis is intact, and the dermis is intact. The phrase "stratum corneum" was removed because it was an error and was inconsistent with the rest of the specification, including the patents incorporated by reference. Removal of the phrase "stratum corneum" did not add new matter.

The Examiner maintains that the instant claims are not enabled to prevent healing of the skin indefinitely and the process of treatment by prevention of healing. The instant claims do not have any steps or elements which claim prevention of healing indefinitely or a process for preventing healing. Therefore, they do not need to be enabled in that regard. The applicant has provided an explanation as to how the process might work, but it is not necessary for one of ordinary skill in the art to know how the process works to duplicate the steps of the methods. If one of ordinary skill performs the steps of the method of claim 1, a, b, c, and d, then the result will be sustained skin rejuvenation. It is not necessary for the practitioner to do anything else to

achieve that result. The specification is clearly enabled for one of ordinary skill in the art to carry out those steps: initially applying retinoic acid to the skin, then exploding the particles on the skin with one or two pulses of the specific laser light described. It is inherent in those steps that neither hair nor skin will be removed (see below). Thereafter, retinoic acid is applied to the skin 4-16 times per month, and the method of exploding the particles on the skin is repeated at least once every 6 months. It is inherent in those steps that rejuvenation of the skin will result. Although the Applicant has offered an explanation as to what she believes causes that result, i.e., increased collagen formation in the high dermis, it is not necessary to know that or to measure it to practice the invention.

The Examiner maintains that the Tankovich patent U.S. Patent No. 6,036,684 "discloses that a single pulse using a graphite particle, which is exploded violently upon being illuminated by vaporizes, i.e., removes, remove a first layer of skin, the second pulse vaporizes the second layer of skin and so forth. Therefore, the state of the art indicates that the same process does remove some skin." The Applicant respectfully disagrees.

The Tankovich patent, U.S. Patent No. 6,036,684, in column 4, describes the method for exploding particles:

"The next step is to irradiate the skin surface with Nd:YAG laser pulses of about 3 J/cm^2 at a wavelength of 1.06 micrometers. Pulse frequency is about 5 Hz but we scan the beam so that each location is subjected to pulses at a frequency of about 1 Hz. Thus, as a result of the first pulse 7 the first layer of graphite particles is exploded as shown at 8 in Fig. 3E. The second layer and the skin surface are effectively shielded from the first pulse 7 by the first layer. Some of the carbon particles above the skin have been pushed into the skin as a result of the shockwaves resulting from the explosion of the particle in the first layer. The second pulse 9 coming one second later, vaporizes the

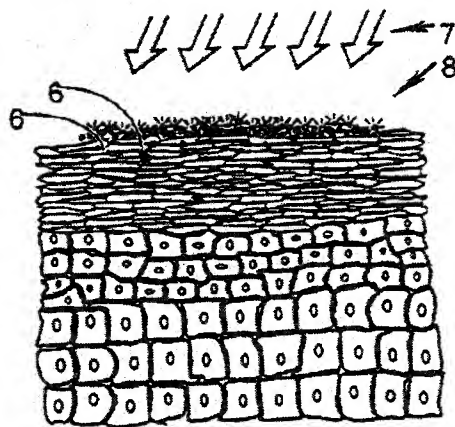


FIG. 3E

second layer as shown at 10 in Fig. 3F. As before, additional particles are pushed into the skin. The skin is fairly effectively shielded from pulse 9 by the second layer. But the third

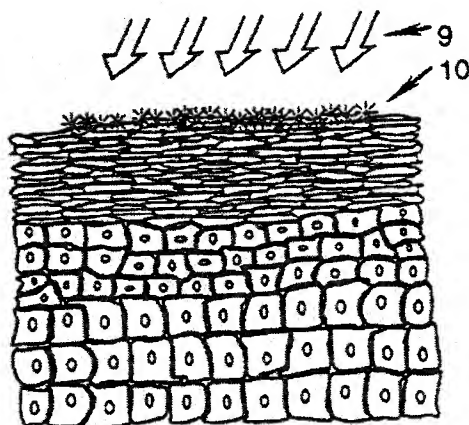


FIG. 3F

pulse 11 interacts with the skin and the carbon particle below the skin. Laser energy at a 1.06 wavelength has an extinction length in human skin of several millimeters but it is highly absorbed in the graphite particles below the surface and upon absorption of the energy from third pulse 11 as shown in FIG. 3G, the particles explode violently ripping

off the dead cells of the stratum corneum which lay above the exploding cells all as shown in FIG. 3H."

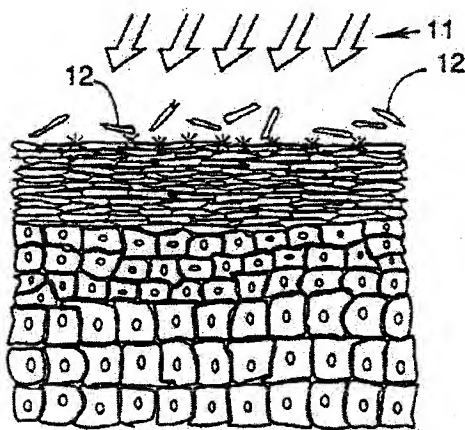


FIG. 3G

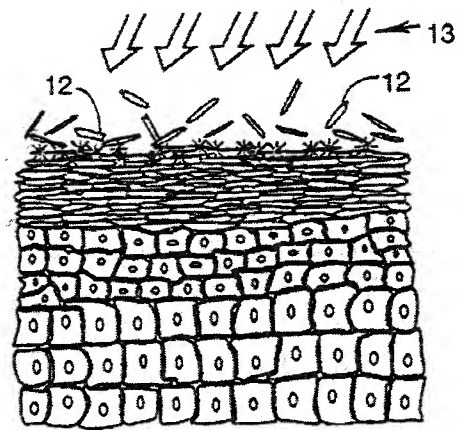


FIG. 3H

In column 5, lines 44-49, it states that "The first or second pulses clean substantially all of the mixture from the skin surface by violently fracturing the carbon particles. By observing how many particles remain, the doctor can estimate the degree to which each area has been treated." Thus, a practitioner need only pass the laser light across the skin sufficient to only clean off the mixture of particles from the skin. This is a simple indication that only 1 or 2 pulses of laser light have been exposed to each area of the skin. Fig. 3 of the originally filed specification at step 43 states "move laser across skin to explode the graphite particles and reveal the underlying skin".

It can be seen in Fig. 3E that the first pulse 7 of laser light explodes a first layer of particles and no skin cells are removed. In Fig. 3F a second pulse of laser light explodes a second layer of particles and no skin cells are removed. In Fig. 3G a third pulse of laser light explodes particles that have been forced into the skin which removes some of the stratum corneum skin cells 12. Since Applicant's method uses only one or two pulses of light per area of skin as shown

in Figs 3E and 3F, Applicant's method does not remove skin. Also, Tankovich teaches that for hair removal, 5 pulses per area of skin are required. In column 5, lines 43-44 Tankovich states that "the beam is scanned over the area to be treated with each section of skin in the area receiving about 5 pulses. Since Applicant's method uses only one or two pulses of light per area of skin, Applicant's method also does not remove hair. In other words, it is inherent in Applicant's procedure itself, where only one or two pulses per area of skin are used to explode the particles, skin and hair are not removed. It is for this reason that this method of Tankovich, where only one or two pulses of light per area of skin are used to explode the particles, is not useful by itself to produce any cosmetic effect or rejuvenation of the skin. The only methods of Tankovich that are cosmetically useful are ones that remove some skin or hair.

The Examiner states that the prior art indicates that some skin either in the stratum corneum or beneath the stratum corneum will be removed by laser surgery. Even if that is the case, the Applicant's method of skin rejuvenation is not a form of laser surgery. The laser light in Applicant's method does not surgically remove any skin. This is also taught by Tankovich, which is recited in the original specification (page 2, lines 9-10 and 16-18): "Exposure of the skin to this type of laser treatment by itself has no effect on the skin because the skin has no inherent target at the 1064 nm wavelength.....There is no significant injury to the skin tissue because the laser energy which is not absorbed in the carbon is harmlessly dissipated in the skin. The low fluence of 2.5 J/cm² leaves the epidermis intact and the typical adverse effects of laser treatment do not occur."

The Examiner states that the specification does not contain working examples. The Applicant respectfully disagrees. Fig. 4 and its description in the specification on page 10, lines 7-17 provide an example of the Applicant's method applied to a subject with lesions and scars on the skin of her face. At lines 2-4, the specification states "The before picture shows the patient's skin after the first six months of treatment of the skin with the method and process of the present

invention.” Because this example is of the use of the method of Applicant’s invention for a period of only 6 months, claim 1 has been amended to recite 6 month’s instead of 12 months.

The Examiner maintains that the lack of significant guidance from the specification or the prior art with regard to preventing the removal of any skin by exploding a contaminant using lasers makes practicing the instant invention unpredictable. The Applicant respectfully disagrees. As noted above, limiting the number of pulses of light to one or two on any area of the skin to explode the particles on the skin will not remove any skin. “The first or second pulses clean substantially all of the mixture from the skin surface by violently fracturing the carbon particles. By observing how many particles remain, the doctor can estimate the degree to which each area has been treated.” (In Tankovich, U.S. Patent No. 6,036,684 col 5, lines 44-49). Fig. 3 of the originally filed specification at step 43 states “move laser across skin to explode the graphite particles and reveal the underlying skin”.

Claim Rejections 35 U.S.C. § 103

The Examiner rejected claims 21, 23-29, and 33-37 under 35 U.S.C. § 103 (a) as being obvious over Goldberg in view of Alster, Ho, and Kye.

The Examiner states that Goldberg teaches a nonablative skin resurfacing method which uses carbon particles exploded by a laser light. The method used by Goldberg appears to be identical to the method taught by Tankovich in U.S. Patent No 5,423,803 titled “skin surface peeling process using laser”. Goldberg states “The treatment involved applying a carbon suspension to the skin surface and irradiating the exogenous chromophore with a Q-switched Nd:YAG laser” using the same laser parameters as Tankovich. This is a method of resurfacing the skin by means of exploding particles sufficient to remove skin cells from the stratum corneum. Tankovich teaches that the laser parameters used by Goldberg would not have a direct effect on the skin. Applicant disagrees that Goldberg teaches a nonablative skin resurfacing. The word “nonablative” does not appear in the reference. In fact, Goldberg’s method requires the

removal of some skin, such as peeling, because resurfacing the skin with exploding carbon produces a cosmetic effect only when some surface skin cells are removed, as taught by Tankovich in U.S. Patents 5,423,803 and 6,036,684. The Examiner states that Goldberg does not disclose the number of passes of the laser over the skin of the patient and the Examiner concludes from this that Goldberg must pass the laser only once. Goldberg does not mention passing the laser at all so there is no way to determine from the reference how many passes Goldberg used. It is clear, however, that Goldberg must use more than two pulses per area of skin treated otherwise there would be no removal of skin by exploding particles and, therefore, no cosmetic effect, as taught by Tankovich. Thus, Goldberg uses a method of exploding particles on the skin to produce some removal of the skin which, in turn, produces a cosmetic effect. The Examiner states that mild rhytides would only require one pass of the laser. The Examiner does not provide any evidence to support this statement. Even if only one pass were required, more than two pulses of laser light would be required to produce a beneficial effect on rhytides, as taught by Tankovich.

The Examiner states that Alster teaches combining laser resurfacing with long-term skin care using tretinoin emollient cream provides maximal, long-lasting improvement of facial rhytides (wrinkles) to provide a youthful look. Over Goldberg and further in view of Ho and Kye the Examiner concludes that it would be obvious to combine tretinoin to work in conjunction with laser treatment to provide long lasting results.

Alster teaches the use of tretinoin pre- and post-operatively with laser surgery where the laser surgery removes skin. Ho and Kye also teach the use of tretinoin pre- and post-operatively with laser surgery where the laser surgery removes skin. In fact, the Examiner states that the prior art indicates that some skin either in the stratum corneum or beneath the stratum corneum will be removed by laser surgery. Furthermore, Alster, Ho, and Kye teach that tretinoin is useful in procedures using laser light only when the laser light directly affects the skin by heating the skin, which is the mechanism by which laser surgery works. Alster, Ho, and Kye do not teach that tretinoin is useful in procedures where laser light does not heat the skin or where the skin is

heated only by exploding particles. The procedures of heating the skin with laser light or heating the skin with exploding particles are not equivalent procedures. Therefore, it is not obvious from Alster, Ho, and Kye that pre- and post-treatment with tretinoin would be useful with the procedure of Goldberg for heating the skin with exploding particles. There is no suggestion or teaching in Alster, Ho, and Kye to motivate one of ordinary skill in the art to use tretinoin in combination with a procedure that heats the skin only by exploding particles. Thus, there is no basis to combine Alston, Ho, and Kye with Goldberg, and Applicant's method is therefore not obvious over Goldberg in view of Alston, Ho, and Kye.

Alston, Ho, and Kye teach that the pre- and post-operative treatment with tretinoin would be useful only when skin is removed. Alston, Ho, and Kye do not teach that the pre- and post-treatment with tretinoin would be useful with a procedure that does not remove skin. It is not obvious from Alston, Ho, and Kye that pre- and post-treatment with tretinoin would be useful in combination with a procedure that did not remove skin. There is no suggestion or teaching in Alston, Ho, and Kye that would motivate one of ordinary skill in the art to use tretinoin preoperatively and postoperatively with a procedure that did not remove skin. Applicant's exploding particle procedure does not remove skin. Therefore, Applicant's method is not obvious over Goldberg, in view of Alster, Ho, and Kye.

Alston, Ho, and Kye teach that the pre- and post-operative treatment with tretinoin would be useful only when the laser procedure by itself produces a beneficial cosmetic effect. Alston, Ho, and Kye do not teach that the pre- and post-operative treatment with tretinoin is useful where the laser procedure by itself does not produce a beneficial cosmetic effect. Applicant's method of exploding particles on the skin by itself does not produce a beneficial cosmetic effect. There is no teaching or suggestion in Goldberg, in view of Alster, Ho, and Kye that pre- and post-operative treatment with tretinoin would be useful in combination with an exploding particle procedure which, by itself, had no beneficial cosmetic effect on the skin. The expectation of one

of ordinary skill in the art is that such a combination would be a waste of time and that the effects with the application of tretinoin would be no better than if the exploding particle procedure of Applicant were not used with tretinoin. Thus, Goldberg in view of Alster, Ho, and Kye do not provide any motivation to one of ordinary skill in the art to combine pre- and post-operative treatment with tretinoin with an exploding particle procedure which, by itself, does not produce a beneficial cosmetic effect. Thus, Applicant's method which uses an exploding particle procedure which, by itself, produces no beneficial cosmetic benefit and which does not remove skin is not obvious over Goldberg in view of Alster, Ho, and Kye.

As noted above, Alster teaches that combining tretinoin with laser surgery, which, by itself, produces a beneficial cosmetic effect through the removal of skin by means of heat, produces a further beneficial effect compared to using tretinoin alone or laser surgery alone. However, heating the skin to the point where skin is removed is undesirable because of the pain and discomfort associated with skin removal and the potential of damaging the skin. Alster does not teach the continued use of the laser treatment, but only the continued use of tretinoin. Thus, over time, the combined effect of tretinoin and laser surgery diminishes and the only benefit of tretinoin treatment remains.

The Applicant has discovered a way to combine the benefits of tretinoin with the benefits of applying heat to the skin without removing skin, but still achieve the combined benefits described by Alster. This was a truly inventive step by the Applicant because there was nothing in the prior art to suggest how this might be accomplished. Applicant's exploding particle method can be used repeatedly along with the repeated use of tretinoin to obtain the continued benefit of the combination of tretinoin treatment and heating the skin with exploding particles. This is so because Applicant's method of exploding particles on the skin does not produce pain or discomfort and does not remove skin. One of ordinary skill in the art would understand that Applicant's method of heating the skin by exploding particles on the skin could be used

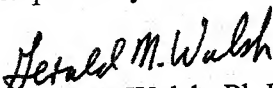
repeatedly without risk of damaging the skin because no skin is removed. Applicant's method of combining tretinoin treatment with heating the skin by exploding carbon particles without removing skin provides a novel and nonobvious method of rejuvenating the skin without the pain and discomfort and without the risk of damage associated with the laser methods in the prior art.

Claim 21 at step b) has been amended to delete the word "pass" and at b) and d) to recite "one or two pulses of laser light". This amendment is supported by the amended specification pursuant to 37 C.F.R. § 1.57 wherein U.S. Patent No. 6,036,684 was incorporated by reference into the specification. Claim 21 at step d) has been amended to recite "6 months" instead of "12 months". This amendment is supported in the specification in Fig. 3, step 44; page 9, lines 17-19; and page 10, lines 8-10. These amendments are responsive to the objections and rejections of the Examiner so that claim 21 is allowable. Claims 23-29 and 33-37 are also allowable as depending from an allowable claim.

CONCLUSION

For the foregoing reasons Applicant respectfully requests that the Examiner reconsider the application in light of the amendments and that all claims in the application be permitted to proceed to allowance.

Respectfully Submitted,


Gerald M. Walsh, Ph.D.
Reg. No. 34,946
Attorney for Applicant
Phone: (205) 972-0145
Facsimile: (205) 972-0163